

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of: Ferree

Serial No.: 10/679,667

Group No.: 3732

Filed: Oct. 6, 2003

Examiner: A. Reimers

For: MULTIAXIAL ARTIFICIAL DISC REPLACEMENTS

APPELLANT'S APPEAL BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I. Real Party in Interest

The real party and interest in this case is Dr. Bret A. Ferree, Applicant and Appellant.

II. Related Appeals and Interferences

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

The present application was filed with 15 claims. Claims 4-15 have been canceled. Claims 1-3 are pending, rejected and under appeal. Claim 1 is the sole independent claim.

**IV. Status of Amendments Filed Subsequent
Final Rejection**

No after-final amendments have been filed.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed to a multiaxial artificial disc replacement (ADR), comprising a

lower component (i.e., 104') adapted for fixation to an inferior vertebral body; an upper component (i.e., 104) adapted for fixation to a superior vertebral body; and cruciate-shaped axle (i.e., 102) that allows movement between the lower and upper components along only two separate, independent axes. (Specification, page 2, lines 10-23; Figures 4 and 10).

VI. Grounds of Objection/Rejection To Be Reviewed On Appeal

1. The rejection of claims 1-3 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,759,769 to Hedman et al. in view of U.S. Patent No. 6,231,609 to Mehdizadeh.

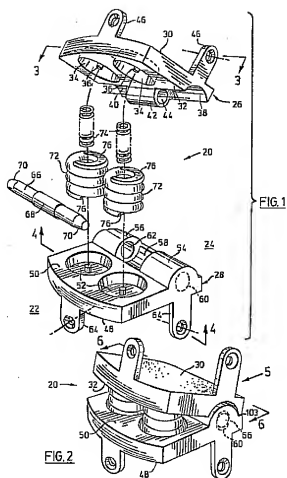
VII. Argument

1. The rejection of claims 1-3, wherein claims 2-3 stand/fall with claim 1.

Claim 1 is directed to a multiaxial artificial disc replacement (ADR) including the limitation of "a cruciate-shaped axle that allows movement between lower and upper [endplate] components along only two separate, independent axes." The claim stands rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,759,769 to Hedman et al. in view of U.S. Patent No. 6,231,609 to Mehdizadeh.

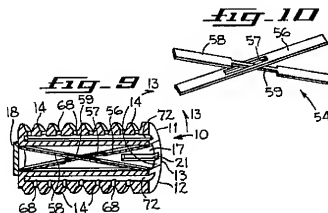
Hedman resides in an artificial spinal disc that arguably meets the *functional* limitations of claim 1, but not all of the *structural* limitations. Figures 1 and 2 of Hedman are reproduced on the next page. The Examiner is correct that device of Hedman et al. includes "a lower [28] component adapted for fixation to an inferior vertebral body" and "an upper component [26] adapted for fixation to a superior vertebral body." However, as the Examiner concedes, Hedman fails to disclose a "cruciate-shaped axle." Even so, the device of Hedman allows for forward/backward pivoting and side-side pivoting, but it does so with a *single axle 66*. According to the reference:

"There is a clearance ... between the hinge pin 66 and the outer elliptical apertures 60, 62. This clearance allows a small amount of side to side rocking of the upper and lower members 26, 28 with respect to each other about a vertical front to rear plane through the center of the members 26, 28 (as shown in FIG. 7). This helps to prevent damage between the parts, and as an incidental effect it allows the patient a small amount of sideways bending at the location of the artificial disc. The tapered or "cigar-shaped" ends 70 of the hinge pin 66 ensure that undue pressure is not concentrated on a single point during sideways bending, and also reduce edge stresses in the hinge pin." ('769 Patent, 4:22-64, cited by the Examiner.)



To meet the limitation of Appellant's "cruciate-shaped axle," the Examiner attempts to import the teachings of Mehdizadeh, U.S. Patent No. 6,231,609. Mehdizadeh teaches a disc replacement prosthesis which is placed within the intradiscal space and which protects remaining discs from deterioration by providing a shock absorbing prosthesis portion. ('609 Patent, Abstract.) With reference to FIG. 10 of Mehdizadeh, shown below, "a crossed spring assembly shown generally at 54, includes a first flat spring 56 having a centrally located aperture 57 therein. A second flat spring 58 is also included having a reduced width section 59 in the center portion thereof. First flat spring 56 is fixed as by welding at an upper end to the under side of upper member 11 and at a lower end to the upper side of lower member 12 as seen in FIG. 9 [also shown below]. The first and second flat springs are assembled within channel 17 by passing the smaller dimension of spring 58 through aperture 57 until reduced width section 59 is within aperture 57 and then rotating spring 58 about its long axis to assume the

attitude seen in FIG. 10. The upper end of second flat spring 58 is then fixed, as previously mentioned, to the under side of upper member 11 and the lower end thereof is fixed to the upper side of lower member 12, whereupon the spring assembly 54 in the configuration of FIG. 10 is fixed within the channel 17 as depicted in FIG. 9.” (‘609 Patent, 3:40-57)



To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

It is Appellant's position that none of the above criteria are met in this case. First, with regard to a suggestion or motivation to combine reference teachings, since Hedman already has a capability to facilitate movement along two axes, it would be superfluous and unnecessary to adopt Appellant's cruciate axle. With regard to "a reasonable expectation of success," there is no evidence whatsoever as to how a "cruciate-shaped spring" could be placed into the Hedman apparatus. Finally, with regard to the proposed combination teaching or suggesting all the claim limitations, a "spring" is simply not "an axle." As such, even if these two references could be brought together, all of Appellant's elements would not be present if the combination were made.

Conclusion

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

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APPENDIX A

CLAIMS ON APPEAL

1. A multiaxial artificial disc replacement (ADR), comprising:
a lower component adapted for fixation to an inferior vertebral body;
an upper component adapted for fixation to a superior vertebral body; and
a cruciate-shaped axle that allows movement between the lower and upper components along only two separate, independent axes.
2. The multiaxial ADR of claim 1, wherein the two axes are orthogonal to one another.
3. The multiaxial ADR of claim 1, wherein one of the axes is generally medial-lateral, and the other axis is generally anterior-posterior.

APPENDIX B

EVIDENCE

None.

APPENDIX C
RELATED PROCEEDINGS

None.